

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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In re: EPHEDRA PRODUCTS LIABILITY : 04 M.D. 1598 (JSR)
LITIGATION :
: OPINION

PERTAINS TO ALL CASES

JED S. RAKOFF, U.S.D.J.

On December 3, 2004, plaintiffs in *Kline v. Metabolife International Inc.*, No. 04 Civ. 3351, and *Westfall v. Metabolife International Inc.*, No. 04 Civ. 4255, moved for certification of a settlement-only class consisting of all persons in the United States who had ingested an ephedra-containing dietary supplement called "Metabolife 356" and for preliminary approval of a class settlement. Defendant Metabolife International Inc. ("Metabolife") joined in that motion and moved separately for an injunction to stay 130 personal-injury actions commenced against Metabolife by members of the alleged class in the courts of many states. Both motions were vigorously opposed by the Plaintiffs' Coordinating Counsel ("PCC") and on April 7, 2005, Metabolife withdrew its motion for an injunction. As to the motion for certification of the settlement-only class and preliminary approval of the settlement, the Court, after receiving extensive written submissions and oral arguments, denied the motion by summary order dated June 2, 2005, with opinion to follow. This is that Opinion.

At the time of its denial of the motion, the Court had before it for consolidated pretrial proceedings about 300 ephedra products liability cases transferred here by the Judicial Panel on Multidistrict Litigation (the "MDL cases"), including some 170 cases against Metabolife (including *Kline* and *Westfall*).¹ In addition, about 60 personal-injury actions against Twin Laboratories Inc. (a onetime manufacturer of ephedra products but unrelated to Metabolife) had been transferred here for trial from state and federal courts pursuant to 28 U.S.C. § 157(b)(5) and were consolidated for pretrial purposes with the MDL cases. Additionally, some 130 ephedra personal-injury cases were pending against Metabolife in various state courts. More than 90 of those were in California, where they had been consolidated for pretrial purposes under a state procedure similar to 28 U.S.C. § 1407.

Against this background, Klein and Westfall filed the instant motions for class certification and preliminary approval of the proposed settlement on December 3, 2004. At oral argument, Metabolife's "settlement counsel" explained the genesis of the motion: Metabolife had retained him to craft a process for settling all 300 state-court and MDL cases involving Metabolife;

¹Metabolife subsequently filed for bankruptcy in the Southern District of California. See Voluntary Petition of Metabolife International Inc. for Chapter 11 Protection, June 30, 2005, Bankr. S.D. Cal.

he first approached the PCC with a proposal, but the PCC expressed a preference for settling cases individually; he then began negotiating with Klein and Westfall's attorneys, who are not members of the PCC.² See transcript, March 16, 2005, at 97-99, 126; see also *id.* at 120-22. Counsel for Klein and Westfall explained that the negotiations were extensive; that they had retained one of the PCC's experts, Christine Haller M.D., to evaluate the proposed matrix of injuries and compensation; and that with her assistance, they had reached settlement terms. See *id.* at 76.

As noted, Kline and Westfall's notice of motion defines the class to be certified as all users of Metabolife 356 (the ephedra-containing product) in the United States, as well as all persons having a derivative claim based on such use. Plaintiffs' Motion for Preliminary Approval fo Class Settlements ¶ 2. A class this broad might number millions, as, according to Metabolife, "Millions of people have consumed Metabolife's ephedra-containing products since 1995." Metabolife's Memorandum of Law on "Phase I" Briefing Issues Relating to Putative Class

²In May 2004, Christopher A. Seeger, Esq., then a member of the PCC, joined the attorneys for Klein and Westfall in an application to serve as counsel for a proposed Metabolife settlement class. The Court denied the motion as premature in the absence of class certification. Mr. Seeger's resignation from the PCC was approved by the Court on December 9, 2004. He was not among the attorneys appearing on behalf of Klein and Westfell.

Settlement and All Writ Injunction at 1. Plaintiffs Kline and Westfall estimate, however, that the settlement class "consists of many *thousands* of persons -- everyone in the United States who was injured by Metabolife's ephedra products or sought treatment from a physician due to concerns about such injuries."

Plaintiffs' Memorandum in Support of Motion for Preliminary Approval of Class Action Settlement at 13 (emphasis added). The difference is that the proposed settlement notice offers a "\$250 Cash Medical Benefit" to users who suffered no injury but have "undergone medical screening by a health care professional in connection with their use" of Metabolife 356.

In any case, the number of users of Metabolife 356 who suffered significant personal injury is likely to be no more than a few hundred persons, i.e., those already in litigation with Metabolife plus a few foreseeable latecomers. This is because a number of factors peculiar to ephedra make it likely that nearly all users of Metabolife 356 who suffered significant personal injury -- or their survivors -- are already plaintiffs in the cases described above. Such factors include: (1) any injury from ephedra, as the experts agree, would manifest itself soon after ingestion (the proposed settlement here at issue set an outer limit of 21 days); (2) the Food and Drug Administration banned ephedra dietary supplements from the market in February 2004, so that the last colorable ephedra injuries occurred more than a

year ago; (3) applicable statutes of limitations tend to be short, as little as one year in some relevant states; and (4) the risk of injury from ephedra has received broad public notoriety, making it unlikely that a user who suffered serious personal injury soon after taking ephedra would be unaware of the possible link and the potential for recourse to litigation.

Before turning to the merits of the instant motion, it should be noted that the Court did not review the proposed settlement for fairness because approval under Rule 23(e)(1)(C), Fed. R. Civ. P., was not *sub judice*. However, at least three procedural aspects of the proposed settlement were relevant to certification. First, the proposed settlement provided a matrix of ten "Injury Categories," each having five possible levels of severity, yielding a total of 50 scheduled benefits. A benefit found in the matrix is then subject to reduction by percentages found in a "Confounding Factor Table," where such factors as prior illness and smoking in various amounts are listed and further defined in 26 footnotes. Second, the proposed settlement provided a multilevel claims resolution procedure: a class member would submit a claim with documentation to a Claims Administrator, who would accept or disallow it; if it were allowed, Metabolife would have the right to demand an audit and interpose an objection; disputes between class members or Metabolife and the Claims Administrator would be referred for a

hearing to a Special Master appointed by the Court upon approval of the settlement. Disputes were foreseeable over product identification, timing of symptoms, diagnosis, severity of injury, and confounding factors. Third, the proposed settlement gave Metabolife the right to "walk away" at any time up to twenty days after 50% of all registered claims had become final by exhaustion of the dispute procedure.

Turning then to the merits, the Court notes first that what the movants here initially sought was to have the Court in effect invent, purportedly under Rule 23 and the All Writs Act, an alternative to the Bankruptcy Code for granting Metabolife a stay of litigation and discharge of liability while affording only one class of potential creditors an equitable share of Metabolife's limited assets. But even after the withdrawal of the stay motion, the proposed certification could not meet the requirements of Rule 23.

It may be true, as the movants have noted, that the somewhat intractable nature of mass tort disputes has sometimes led some courts to take a relaxed view of settlement-only class certifications. Nonetheless, in the only two occasions that settlement-only reached the Supreme Court, the Court held certification improper. *Ortiz v. Fireboard Corp.*, 527 U.S. 815 (1999); *Amchem Prods. v. Windsor*, 521 U.S. 591 (U.S. 1997). Indeed, the *Amchem* decision was expressly intended to curb

"judicial inventiveness" of the kind requested here, 521 U.S. 591 at 619, and to restrict district judges' discretion to do equity under the guise of Rule 23. "The safeguards provided by the Rule 23(a) and (b) class-qualifying criteria ... serve to inhibit appraisals of the chancellor's foot kind -- class certifications dependent upon the court's gestalt judgment or overarching impression of the settlement's fairness." *Id.* at 621.

In *Amchem*, the Court also rejected the argument made by the movants here that certification requirements are relaxed when litigation is to be obviated by a settlement. "[P]roposed settlement classes sometimes warrant more, not less, caution on the question of certification." *Id.* at 620 n.16. Indeed, *Amchem* allowed only one exception to the strict application of Rule 23(a) and (b) to settlement-only classes:

Confronted with a request for settlement-only class certification, a district court need not inquire whether the case, if tried, would present intractable management problems, see Fed. Rule Civ. Proc. 23(b)(3)(D), for the proposal is that there be no trial. But other specifications of the Rule -- those designed to protect absentees by blocking unwarranted or overbroad class definitions -- demand undiluted, even heightened, attention in the settlement context.

Id. at 620.

As a fall back to their unpersuasive argument that Rule 23 should be relaxed in assessing a settlement-only class, movants also argue that the threshold for certification should be

relaxed because they are asking for only preliminary approval of a settlement -- just enough approval to disseminate its terms to class members -- together with an initial certification that is subject to decertification later. They rely on a number of district court cases that granted conditional certification along with preliminary approval a settlement. However, an amendment to Rule 23 in 2003 Amendment deleted the provision that a class certification "may be conditional." According to the Advisory Committee that drafted the change, the change was made because a "court that is not satisfied that the requirements of Rule 23 have been met should refuse certification until they have been met." See Rule 23, Fed. R. Civ. P., Advisory Committee Notes to 2003 Amendments. Thus, Rule 23 must be rigorously applied even at this "preliminary" stage.

Application here of Rule 23 standards reveals that the proposed certification is deficient for, *inter alia*, some of the same reasons addressed in *Amchem*. In particular, with respect to what is called the "predominance test" -- that is, the requirement that "questions of law or fact common to the members of the class predominate over any questions affecting only individual members," see Rule 23(b)(3) -- the Supreme Court found that the following facts present in *Amchem* served to negate predominance of common questions:

Class members were exposed to different asbestos-containing products, for different

amounts of time, in different ways, and over different periods. Some class members suffered no physical injury or have only asymptomatic pleural changes, while others suffer from lung cancer, disabling asbestosis, or from mesothelioma. . . . Each has a different history of cigarette smoking, a factor that complicates the causation inquiry.

Id. at 624. Here, similar disparities among ephedra users are evident in the proposed settlement. If it were implemented, innumerable questions affecting individual class members would arise -- including whether the product they used was Metabolife 356, the time between product use and the onset of their symptoms, their diagnosis, the severity of their injury, the number of cigarettes they smoked daily, etc. -- all of which would have to be resolved in determining the amount of compensation they would receive. Not only would these individual questions predominate among members of the proposed settlement class, they would be the only questions having any weight, since class members' common interest in a fair, reasonable and adequate settlement is not a question to be considered under the predominance test. See *id.* at 622.

"The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation" and "is similar to the requirement of Rule 23(a)(3) that 'claims or defenses' of the named representatives must be 'typical of the claims or defenses

of the class.' " *Id.* at 623 & n.18. Here, the proposed "Settlement Class" ranges from users who suffered no injury at all to the survivors of those who suffered death. Such a class is not sufficiently cohesive to warrant adjudication by representation. Even if the class were redefined to cover only users eligible for a matrix benefit, individual questions of diagnosis, severity and confounding factors would still predominate.

Furthermore, in order to certify a class under Rule 23(b)(3), the court must find

that that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) [not applicable to settlement-only certification].

The three pertinent matters, applied to the circumstances here, show that a class action is not superior to individual civil actions:

Matter (A). Members of the PCC have asserted the interest of their clients -- both MDL plaintiffs and plaintiffs in state courts -- to control the prosecution of their claims and negotiate individual settlements. As the Supreme Court observed

in *Amchem*, quoting the Third Circuit decision it was affirming:

"'Each plaintiff [in an action involving claims for personal injury and death] has a significant interest in individually controlling the prosecution of [his case]'; each 'ha[s] a substantial stake in making individual decisions on whether and when to settle.'" 521 U.S. at 616 (brackets in original). The same is true here.

Matter (B). As already noted, it is probable that nearly all the real class members in interest -- users of Metabolife 356 who suffered personal injury or their survivors -- are already plaintiffs, and that most are already before this court. This circumstance shows that joinder of all personal-injury claimants in individual actions is practical -- a reason for denying certification similar to the numerosity requirement of Rule 23(a)(1). It also means that certifying the class will not provide remedy that prevents the commencement of multiple individual lawsuits.

Matter (C). Here, prior to Metabolife's bankruptcy, the alternative to a class action (for all but about 30 of the 300 personal-injury cases) was the existing MDL and its California counterpart. Concentrating dispute resolution in one forum is desirable for resolving common issues but undesirable for questions peculiar to individual class members. The MDL procedure accommodates both interests through pretrial

consolidation followed by remand to the transferor courts for trials that may require the participation of fact witnesses and treating physicians. A similar bifurcated forum is available under California procedure for the 90 state cases consolidated there. The proposed class settlement, with its centralized hearings before a Special Master that may involve fact witnesses and treating physicians, would not be superior in terms of forum concentration to resolving such disputes in the transferor courts.

Accordingly, for the foregoing reasons, the Court, on June 2, 2005, denied the motion of Kline and Westfall for class certification of a settlement-only class and preliminary approval of the settlement.



TED S. RAKOFF, J.S.D.J.

Dated: New York, New York
September 11, 2005